REMARKS

Reconsideration and withdrawal of the rejections of and objections to the application are respectfully requested in view of the amendments and remarks herewith, which place the application in condition for allowance.

Claims 1, 16-19 and 21-29 are pending. Claim 1 is amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments of the claims as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations are found throughout the specification.

As this paper is being submitted within the three-month term for reply set by the March 4, 2002, Office Action, no fee is believed to be due. In the event if a fee is occasioned by this paper, such fee, or any overpayment herein, may be charged or credited to Deposit Account No. 50-0320.

Claim 18 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. The rejection is traversed.

The amended recitation to claim 1 is made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, have rendered the rejection of claim 18 moot.

Claims 1 and 16-29 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 5,965,155 ("hereafter the '155 patent"), or U.S. Patent No. 5,869,089 "hereafter the '089 patent") in view of any of U.S. Patent No. 4,753,648 ("hereafter the '648 patent") or U.S. Patent No. 4,358,494 ("hereafter the '494 patent"). The rejection is traversed. None of the cited documents teach, suggest, disclose or motivate a skilled artisan to practice the instantly claimed invention.

The present invention is directed to, *inter alia*, a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine, acrylate and a copolymer wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer. Neither the '155 patent nor the '089 patent, nor the'648 patent nor the '494 patent either alone or in combination, teach suggest, disclose or motivate a skilled artisan to practice the instantly claimed invention.

Contrary to the view of the Examiner, the '155 patent does not disclose a multi-layered transdermal patch for the treatment of migraine, said patch comprising contact adhesive layer comprising clonidine...". The '155 patent is directed to a process for its production for a transdermal application in the prophylaxis and treatment of vasodilations, said pharmaceutic product comprising at least one skin-compatible auxiliary agent and portions of an active substance pentetrazole. Moreover, the '155 patent clearly discloses that there is no single remedy for the prophylactic treatment of all forms of migraine and therefore teaches away from using clonidine for the treatment of all forms of migraine.

Indeed, clonidine is merely cited in the '155 patent as one of many active agents that may be used to prevent migraines. There is no teaching or suggestion in the '155 patent that would motivate one of ordinary skill in the art to incorporate clonidine into any transdermal system let alone the transdermal system as presently claimed.

The '089 patent relates to a method for membrane controlled programmable trans-dermal therapeutic systems (PTTS), which comprises a supersaturated drug solid solution system and easily adjustable controlled release membrane which contains clonidine for reducing opiate withdrawal symptoms. More specifically, the PTTS of the '089 patent specification states at col. 2, lines 28-38 that "This invention adopts a series of special technology which provides formation of a highly stabilized supersaturated solid polymer solution. This is **the basic prerequisite for realizing a TTS with high initial release rate and decreasing release rate** with time. In order to realize the requirement of decreasing release rate with a pre-determined schedule, **it is necessary to use a type of controlled release membrane** with correspondingly matched release rate selected from a series of controlled release membranes with easily adjustable release rate in broad range." (emphasis added).

In essence the '089 patent would deter a skilled artisan from constructing the presently claimed transdermal system **consisting essentially** of 1) **a pressure-sensitive contact adhesive**

layer comprising clonidine, acrylate and a copolymer wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate; 2) **a covering**; and on a side opposite from the covering; and 3) **a removable support** that temporarily covers the contact adhesive layer because the present invention does not contain a controlled release membrane, which the '089 patent asserts is necessary for a TTS with a high initial release rate and decreasing release time. Indeed, it was surprisingly found that a pressure-sensitive acrylate-based contact adhesive, which consists of the monomers 2-ethylhexyl acrylate and vinyl acetate maintains adequate flow of the active ingredients over a period of seven days (see specification at page 5, lines 11-26) without the need for a controlled release membrane.

The '648 patent concerns a sanitary napkin and does not teach or suggest any type of transdermal system, let alone a transdermal system as presently claimed for the delivery of clonidine. Therefore the '648 patent is irrelevant to the present invention and contrary to the view of the Examiner the '648 patent would not provide the motivation to a skilled artisan to incorporate an adhesive composition into the transdermal system as presently claimed.

The '494 patent describes the preparation of a pressure-sensitive adhesive tape for sealing the flaps of a corrugated box. There is no teaching or suggestion of the incorporation of this tape or adhesive layer into any type of transdermal system let alone the transdermal system as presently claimed. Again the '494 patent is irrelevant to the present invention and would not provide the motivation to a skilled artisan to incorporate a pressure-sensitive adhesive tape or adhesive layer into the transdermal system as presently claimed.

More specifically, neither the '155, the '089, the '648 nor the '494 patents teach or suggest a transdermal system as presently claimed.

It is respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the**

claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

None of the cited references satisfy the requirements for obviousness. None of the references possess the requisite suggestion or disclosure that would lead a skilled artisan to practice, *inter alia*, a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine, acrylate and a copolymer wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer.

The cited documents in other words, do not lead a skilled artisan to practice the instant invention. Thus, it is respectfully submitted that the obviousness rejection simply cannot stand.

Consequently, reconsideration and withdrawal of the Section 103 rejection are believed to be in order and such actions are respectfully requested.

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview is respectfully requested; and, the Examiner is further respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for the interview.

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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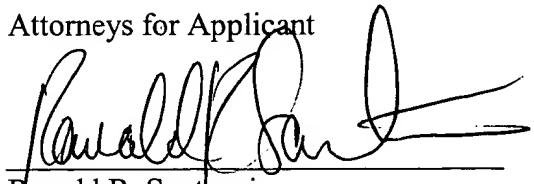
By: 

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VERSION TO SHOW CHANGES MADE

1. (Amended) A transdermal system for the delivery of clonidine consisting essentially of

a [clonidine-containing,] pressure-sensitive[, acrylate-based] contact adhesive layer comprising clonidine, acrylate and a copolymer [consisting of the monomers] wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate;

a covering; and

on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer.